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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/815,582	FREEDMAN, BRIAN	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☒ Claim(s) 4 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 31 Mar 2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims

Claim Objections

Claim 4 is objected to because of the following informalities: the term "tetrasodudium" is misspelled; the term should read "tetrasodium". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 16 and 17 recite the limitation "hydrogen peroxide" in second line of each claim. The independent claim, claim 10 makes reference to a bleaching agent, but the dependent claims do not define the bleaching agent. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1, 4, 6 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Feringa et al. (US 5,580,485).

Feringa et al. teach bleach and oxidation catalyst that can activate hydrogen peroxide or peroxy acids, which improve clothes detergents. The Fe complexes disclosed by the reference may be included in bleaching systems comprising a peroxy compound or precursor. The iron catalyst shifts the pH of the compositions to neutral values (col. 3, line 1-2), which include 7 as recited by the instant claims. The detergent bleach composition according to the present invention generally contains a surface-active material in an amount from 10 to 50% by weight (col. 6, lines 5-7), as recited in claim 8. The composition of the invention normally and preferably also contains a detergency builder. Builder materials may be selected from calcium sequestrant materials, such as alkali metal polyphosphates, such as sodium tripolyphosphate; nitrilotriacetic acid and its water-soluble salts; the alkali metal salts of carboxymethyloxy succinic acid and ethylene diamine tetraacetic acid (col. 7, lines 11-25), which encompasses claim 4. Of the additives, transition metal sequestrants, such as EDTA

are of special importance, as not only do they improve the stability of the catalyst/H_2O_2 system and sensitive ingredients, such as enzymes, fluorescent agents, perfumes and the like, but also improve the bleaching performance, especially at the higher pH region of above 10, particularly at pH 10.5 and above (col. 8, lines 12-19). This indicates the compositions are above 7 and fall within the range of 10.3 and 10.8 as recited in claim 6. The hydrogen peroxide solutions added to the compositions were aqueous, therefor encompassing claim 9. The reference anticipates the claims insofar as it anticipates compositions comprising heavy metal complexes and chelators at a pH of at least 7.

2) Claims 1-2, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Bragg (US 4,430,243).

Bragg teaches laundry bleaching and detergent compositions comprising a peroxygen bleaching agent and a catalyst system. The catalyst system comprises a heavy metal cation of defined bleach catalytic activity, particularly copper, iron or manganese cations, an auxiliary metal cation having little or no bleach catalytic activity, particularly zinc or aluminum cations, and a sequestrant having defined stability constants for the catalytic and auxiliary metal cations, particularly ethylenediamine tetraacetic acid, and water-soluble salts thereof (see Abstract), which encompasses claims 1-2 and 4. The present invention provides a catalyst composition for a peroxygen bleaching agent, the composition being soluble in water at pH 10 and being characterized by: a catalytic heavy metal cation having a catalytic activity for decomposition of the peroxygen bleaching agent of at least 10%; an auxiliary metal

cation having a catalytic activity for decomposition of the peroxygen bleaching agent; and a sequestrant. Highly preferred catalytic heavy metal cations are cations of copper (especially Cu(II)), iron (especially Fe(III)) and manganese (especially Mn(III)), which encompasses claim 2. Preferred sequestrants are ethylenediamine tetraacetic acid, diethylenetriamine-pentaacetic acid, and alkali-metal and alkaline-earth metal salts thereof, which encompasses claim 4. The sequestrant component of the present compositions is a multi-dentate ligand forming a complex with both the catalytic heavy metal cation and the auxiliary metal cation. Both complexes are soluble in water at pH 10 (col. 2, lines 25-38). Therefore it can be concluded the compositions were aqueous solutions to determine their pH, which was greater than 7 as recited by the instant claims. The present invention also provides laundry bleaching and detergent compositions comprising the catalyst composition described herein. The laundry bleaching compositions of the invention contain from about 5% to about 99.95%, preferably from about 20% to about 95% of peroxygen bleaching agent and from about 0.05% to about 5%, preferably from about 0.1% to about 2% of catalyst composition. The peroxygen bleaching component may be chosen from a group including hydrogen peroxide (col. 7, lines 60-61). A wide range of surfactants can be used in the present laundry compositions (col. 8, lines 15-16), encompassing claim 8. For optimum performance, the laundry bleaching and detergent compositions are preferably buffered to a pH in 1% solution of at least about 9.5, preferably at least about 10. Although the reference teaches laundry composition, the catalyst solution activates the peroxygen component, such as hydrogen peroxide, which is a criterion for the instant claims. The

compositions disclosed by the reference comprise substantially the same compounds, a chelating agent and a heavy metal, as the compositions disclosed and claimed by the Applicant. Accordingly, one would have reasonably expected that the compositions of the reference may serve the substantially the same function, such as boosting and activating peroxides in tooth whitening, as the applicant's compositions, since the compositions of the reference and the compositions of the instant claims are substantially the same. The reference anticipates the instant claims insofar as it discloses compositions comprising heavy metals and chelators, which have a pH of above 7 in water.

3) Claims 1-4, 6 and 9-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Montgomery et al. (US 6,343,933).

Montgomery et al. teaches compositions and methods to whiten teeth by light activation. One of the taught methods involves applying a photosensitizing containing composition to the teeth followed by an oxidizing agent composition. The compositions are then exposed to light (col. 7, lines 1-4). The photosensitizers include metal-ligands such as manganese gluconate. Especially preferred photosensitizers belong to the general class of water-soluble metal-ligand complexes, which absorb light in the range of from about 350 nm to about 700 nm. Suitable metals ions include iron, manganese, copper, and other transition metal ions. Examples of metal-coordination complexes are formed from the association of iron, manganese and copper with chelators such as ethylenediamine tetraacetic acid (EDTA), which encompasses claims 2 and 4. Any

organic multi-dentate chelating agent capable of forming a photo-absorbing coordination complex with a metal ion can be presumed to have utility in the present inventive compositions and methods of whitening stained teeth. A number of the inventive metal-ligand complexes have an absorption spectrum that is pH-dependent; in general, such complexes will display a greater degree of absorption between 350 and 700 nm at a pH of greater than about 4.0, light absorption in this range increasing with increasing pH. Greater than 4 encompasses claim 6. For instance, the aqueous complex formed between 1-hydroxyethylidene-1,1-diphosphonic acid and ferrous ions is virtually transparent to visible light at pH 3.0, but absorbs strongly in the spectral region between 350 and 500 nm as the pH is raised to 7.0 (col. 7, lines 49-67 and col. 8, lines 1-26). This aqueous composition encompasses claims 1 and 9. A light-activated tooth whitening method, in accordance with a specific embodiment of the invention includes contacting the tooth enamel surface with the photosensitizing agent, then contacting the photosensitizer-treated tooth surface with the oxidizing compound, and, thereafter, exposing the tooth surface to light energy capable of activating the photosensitizer which, in turn, activates the oxidizing compounds at the tooth enamel surface, which encompasses what is recited in claims 10 and 13-14. It can be concluded when the tooth is exposed to light it is heated by the transfer of energy from the light to the tooth. Suitable lamps that emit actinic radiation in the preferred range of wavelengths include Xenon short arc, Mercury short arc and Mercury Xenon short arc, which encompasses claim 15, Argon plasma arc, and Argon short arc lamps, among others. In regards to claims 11-12, it can be concluded the above composition are applied to dry surfaces

due to the fact the teeth are exposed to the air in order to apply to compositions, thereby preventing the teeth from being moistened when the compositions are being applied to the teeth. The oxidizing compounds are liquid, gel, or solid compositions transparent to the wavelength(s) of light capable of activating the photosensitizing agent at the tooth surface. The oxidizing agents that may be used within the oxidizing composition include hydrogen peroxide, which is recited in the instant claims. The examples included hydrogen peroxide in the compositions at 3% and at 15%. It can be concluded the hydrogen peroxide may be present in the compositions from about 3% to about 15%, which encompasses claim 16. Therefore these values encompass claim 16. The reference discloses, within its prior art, professional compositions for whitening teeth with peroxide. The commercial product is supplied in a plastic syringe and is described in the accompanying literature as a light-activated tooth whitening gel, which contains approximately 35% hydrogen peroxide. The product is thickened to a loose, gel-like consistency with a polymer (col. 2, lines 21-29). This encompasses what is recited in claim 17 because it shows an in-office composition for tooth whitening comprising 35%. The reference anticipates the instant claims insofar as it discloses compositions comprising heavy metals and chelators, which have a pH of above 7 in water and methods for whitening teeth using the compositions and peroxides with light.

4) Claims 1-3, 6 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Rerek (US 4,728,455).

Rerek teaches bleaching compositions comprising bleaching agents and bleach activators. The foregoing objects are achieved according to the present invention, which provides novel peroxide bleach catalyst, promoter or activator systems for use in laundry detergent and/or bleaching applications. The bleach catalysts or activators are based on tripositive manganese ion, Mn(III), and are safe to both the consumer and the environment. In addition, the Mn(III)-based compositions described herein are resistant to both hydrolysis and oxidation, thus providing a significant improvement in stability over peroxide bleach catalysts based on dipositive manganese ion, Mn(II). In addition to increasing peroxide bleaching efficacy, the bleach promoters or catalysts of the invention actively inhibit the undesirable peroxide decomposition that occurs in the presence of other manganese species independently of bleaching, thus optimizing bleaching performance for any level of peroxide bleach dosage and minimizing the amount of peroxide bleach necessary to achieve satisfactory bleaching. The manganese complex used in the invention was manganese gluconate made from manganese sulfate and sodium gluconate (col.5, lines 33-44). The catalyst were prepared by preparing an aqueous solution of a source of manganese (III) and a multi-dentate ligand-supplying complexing agent, this can also be a chelating agent, which encompasses claim 9. According to encyclopedia.com, chelating agents are certain organic compounds, which are capable of forming coordinate bonds with metal through two or more atoms of the organic compound. A chelating agent that has two coordinating atoms is called bi-dentate, therefore, multiple coordinating atoms are multi-dentate. The pH of the solution is adjusted to between about 9 to about 12, which

encompasses the instant claims. The solution is agitated in air to form a water-soluble complex of manganese (III) with the multi-dentate ligand. The source of manganese (III) is a manganese (II) salt and the complexing agent is sodium gluconate and the pH is adjusted using sodium hydroxide (see the referenced claims). This encompasses claims 1-3, where manganese is the heavy metal salt and the gluconate is the chelating agent. Although the catalyst are made for a detergent system, the claims recite a composition for activating peroxides in to whiteners, which the catalyst compositions of this invention does because the peroxides used in the reference are substantially the same as those used in the disclosure by the Applicant. Accordingly, one would have reasonably expected that the compositions of the reference have substantially the same effects on peroxide in whitening compositions as the applicant's compositions, since the compositions of the reference and the compositions of the instant claims are substantially the same.

5) Claims 1-3, 5, and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Nabi et al. (WO 99/17734).

Nabi et al. teach compositions for enhancing the antibacterial efficacy or antibacterial dentifrices, comprising preparing a multi-component dentifrice composition (see abstract). The first component comprises and antibacterial agent and a manganese coordination complex compound. The manganese coordination complex includes manganese gluconate. The manganese is complexed with a multi-dentate ligand in order to create the manganese coordination complex (page 6 and 7). The

multi-dentate may also be considered a chelating agent, which encompasses the instant claims. A buffering agent is also used to maintain the pH of the composition, where the pH ranges from about 6.5 to about 7.5. The vehicle for the composition includes water and humectants, therefore making the compositions aqueous. The water content ranges from 8% to 30% of the composition, which encompasses claim 9. Surfactants are also utilized in the compositions, which encompasses claim 8 (page 4). Thickeners may be included in the composition. The thickeners include polyvinylpyrrolidone (page 9, lines 28-30), which encompasses claim 5. The reference anticipates the claims insofar as it discloses a composition comprising a transition metal catalyst and a chelating agent solution with a pH of at least 7. The compositions of the reference are used in combination with peroxide containing dentifrices. Intended use of the transition metal complex composition carries no weight in determining the patentability of the instant claims because the compositions of the prior art can be used for whitening teeth, as recited by the instant claims, as well as enhancing the antibacterial efficacy or antibacterial dentifrices as recited by the reference, since the compositions are substantially the same as the Applicant's compositions.

6) Claims 1, 6 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Nathoo (US 2003/0103913).

Nathoo teaches compositions and methods for the whitening of teeth. The composition comprises a combination of an activator composition and a peroxide containing composition. The activator composition comprises a transition metal such as

zinc. Also included is a chelating agent to form a peroxide activation complex. The compositions are prepared in water and sodium hydroxide is added to increase the pH to about 10, which reads on the claims because the term "about" permits some tolerance. See, for example, In re Ayers, 69 USPQ 109 (CCPA 1946), where "at least about 10%" was held to be anticipated by a teaching of a content "not to exceed about 8%." A thickener was added to the mixture to make a gel composition (paragraph 0041). Although titanium oxide was used in the example, zinc oxide may be substituted as stated in the referenced claims. The reference anticipates the claims insofar as it discloses a composition comprising a transition metal catalyst and a chelating agent solution with a pH of at least 7, for the activation of a peroxide in a tooth whitening composition.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 5-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffer et al. (WO 97/02805) in view of Banerjee (US 2002/0141949).

Gaffer et al. teach a two component whitening dentifrice compositions, which comprise a first component containing a peroxygen compound and a second dentifrice component containing a manganese coordination complex. The manganese complexes comprise of a manganese (III) and a multi-dentate ligand, which are also chelators. The manganese coordination complexes include manganese gluconate, recited in claims 2-3. The two phases are combined shortly before application to the teeth wherein the manganese compound interacts with the peroxygen constituent to accelerate the breakdown and rapid release of active oxygen from the peroxygen compound such rapid release being effective for whitening teeth when allowed to remain on the teeth for a limited time. The amount of manganese complex activator compound present in the second component of the two phase whitening oral composition of the present invention will vary dependent upon the amount of peroxygen compound incorporated in the first component. When the whitening oral composition is to be used by trained professionals and the first component contains relatively high concentrations of a peroxygen compound, e.g. 5 to 35% by weight, the amount of manganese activator compound incorporated in the second component will range between 0.1 to 3%, which encompasses claim 7. For home use oral compositions in which the concentration range of peroxygen compound in the first oral composition component is between about

0.1 to about 3.0% by weight, lower concentrations, e.g., between about 0.001 to about 0.3% by weight of the manganese activator is included in the second component and preferably about 0.0025 to about 0.15% by weight of the activator is used (page 5, lines 1-14). Other components may be added to the manganese complex composition such as surfactants and thickeners, e.g., polyvinylpyrrolidone, as recited in claims 5 and 8. The vehicle may be a mixture of water and humectants and make up 40% - 80% of the dentifrice components. It can be concluded these composition may be aqueous solutions, which encompasses claim 9. A base such as sodium carbonate is also included in the compositions. The reference differs from the instant claims insofar as it does not disclose the pH of the compositions being at least 7.

Banerjee teaches dental bleaching gel compositions having long shelf life for use with an activator system to cause accelerated bleaching action of a peroxide bleaching agent in the bleaching gel composition when applied upon a tooth surface and a method for applying and activating a dental bleaching gel upon a tooth surface for cosmetically whitening the tooth and/or for the treatment of stains or discolorations over a shortened time period (see abstract). The compositions of the disclosed invention is directed to a bleaching composition in the form of a gel for use with an activator system which combines the features of both the "one-part" system and the "two-part" system for providing enhanced and independent control over the rate of activity of the peroxide bleaching agent to whiten teeth without affecting shelf life (paragraph 0006). The activator system of the disclosed invention for activating a bleaching composition containing a stabilized peroxide bleaching agent preferably consists of particles of a

dried compound selected from either a catalyst, an enzyme or a pH modifier to increase the pH to above at least 7. The most preferred activator is a compound selected from the group consisting of Manganous Chloride, Manganous Citrate, Ferrous Sulfate, Sodium Carbonate, Sodium Bicarbonate and Catalase (paragraph 0009). Metal ions such as iron, cobalt, nickel, copper, zinc, manganese, chromium, etc. are known to catalyze the decomposition of hydrogen peroxide in solution, thus unleashing the bleaching action. Of these the chloride salt of manganese seemed to be the most effective in activating the gel. Iron salts were also tried but did not prove as effective, probably due to the lowering of pH of the solution by the iron salt, which in turns tries to stabilize hydrogen peroxide. Managanese salts, on the other hand, when dissolved in water, do not affect the pH of the solution and leads to a controlled destabilization of hydrogen peroxide. In this context, it should be mentioned that literature cites other manganese salts such as citrate and gluconate as activators (paragraph 0032). Hydrogen peroxide is known to get destabilized and release hydroxyl and perhydroxyl free radicals and oxygen gas at a pH greater than 7 into the environment. Thus, raising its pH by adding sodium carbonate or bicarbonate can also activate the gel of the disclosed invention. In the earliest stages of the disclosed invention, baking soda was used to activate the gel. Later, however, the activation with manganese chloride solution proved to be more expedient and more reproducible. The reference differs from the instant claims insofar as it does not disclose the chelators in solutions with the heavy metal salts.

It would have been obvious to one of ordinary skill in the art to have used the sodium carbonate in the manganese gluconate containing composition of the primary reference motivated by the desire to increase the activation of the hydrogen peroxide by raising the pH to above 7 and to ensure the pH remained above 7 so that the peroxide will not be stabilized by a drop in pH as disclosed by secondary reference.

Claims 1-17 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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